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The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

I write on behalf of Plaintiff Shionogi Pharma, Inc. ("Shionogi"), and pursuant to the Court's May 14, 2012 Order (D.I. 444), to outline outstanding discovery issues in advance of the July 13, 2012 court conference.

I. DEFICIENCIES IN LUPIN'S DISCOVERY RESPONSES

Despite Shionogi's extended efforts to compromise and reduce any burden on Lupin, and even though Shionogi has substantially narrowed its document requests, Lupin continues to maintain its categorical refusal to provide legitimate discovery. Accordingly, Shionogi requests that the Court order Lupin to produce, within ten days, each of the significantly-narrowed categories of requested documentary discovery discussed below. Shionogi also requests that the Court award it reasonable expenses, including attorneys' fees, as sanctions on Lupin for its continued refusal to comply with the Court's orders, as addressed below.

A. *Damages-Related Discovery*

1. Background

Lupin continues to maintain its blanket refusal to produce damages-related discovery, despite this Court's prior orders. At the May 11, 2012 hearing, the Court ruled that "there is ***no bar*** to obtaining what has been characterized [by Lupin] as highly sensitive confidential information. This type of information is ***routinely discovered*** in patent cases and has been discovered already in this case, and there is ***no carve-out*** in Federal Rule of Civil Procedure 26 for this information." *See* Ex. A (May 11 Hearing Tr.) at 76:4-10 (emphasis added). Similarly, the Court ruled that Lupin had not established any infirmity in the protective order in this case that would prevent production of information to Shionogi or its counsel. Accordingly, the Court ruled that "***some or all*** of [the requested documents]must be produced in discovery." Ex. A at 78:3-7; *see also id.* at 79:6-16. The Court directed the parties to discuss areas where the requests—which, unquestionably seek relevant information, Ex. A at 78:13-18; 79:6-8—might be narrowed to the satisfaction of both parties. The Court, however, clearly denied Lupin's request for blanket protection for its self-designated "sensitive" documents. *See* D.I. 444 (May 14, 2012 order denying Lupin's motion with respect to all issues except documents related to Lupin's negotiations to sell its ANDA, and instructing the parties to meet and confer regarding individual discovery requests).

Plaintiffs and Lupin conducted a telephonic meet-and-confer on May 24, 2012, during which Shionogi substantially narrowed the scope of its document requests. Yet, Lupin continued to refuse to produce even the narrowed categories of discovery, again reciting that those documents are too sensitive to produce. Shionogi then sought guidance from the Court by letter dated May 30, 2012. On May 31, 2012, the Court reiterated that it had "already denied Lupin's request to bar discovery of all of the requested damage information on the ground that the information is sensitive and confidential," and that it had directed the parties "to meet and confer regarding the specific document requests at issue . . . to attempt to resolve their discovery dispute without intervention of the Court." D.I. 462. The Court also ordered Lupin to "promptly produce the documents it [previously] agreed to produce." *Id.*

On June 5, 2012, the parties held another meet-and-confer during which Lupin offered to provide a grand total of a single spreadsheet containing limited, aggregate information regarding its infringing sales, which Lupin alleged would satisfy its discovery obligations. Shionogi accepted this "offer," but requested Lupin's underlying documents as well so that Shionogi could verify the information provided by Lupin. Moreover, Lupin's "offer" was improperly conditioned on counsel for Shionogi not sharing the information with co-plaintiff Andrx's counsel. During that meet-and-confer, Lupin again failed to provide an estimated date by which it would produce any documents. Despite its representation to the Court and the Court's May 31 Order, Lupin to date still has produced none of these documents, nor has it even provided the spreadsheet as promised to Shionogi's counsel, who informed Lupin that Shionogi would abide by Lupin's disclosure conditions until this Court ruled otherwise.

2. Relevance of Damages Discovery Generally

(a) Lost Profits

As damages for Lupin's patent infringement, Shionogi seeks lost profits, including price erosion. As part of its evidentiary burden, Shionogi must show that "but for" Lupin's infringement, it would have made all or a portion of Lupin's sales. Courts generally consider four factors in the lost profits analysis: "(1) demand for the patented product; (2) absence of acceptable noninfringing substitutes; (3) manufacturing and marketing capacity to exploit the demand; and (4) the amount of profit [Shionogi] would have made." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc). Documents in Lupin's possession that are relevant to this inquiry include:

(a) Lupin's sales and cost data and marketing information regarding the accused products, including number of units sold, gross sales, sales price, rebates/discounts, and net sales of the accused products. Such documents are relevant to the issues of demand for the patented product (of which Lupin's generic copy would be one example) as well as the presence or absence of non-infringing substitutes.

(b) Lupin's agreements and communications with its customers, including the identification of the customers who bought the accused products, documents and information concerning those customers' purchases, as well as market analyses identifying potential competitors (if any) for FORTAMET® and Lupin's generic copy, and sales of those products. Such documents are again relevant to the issues of demand for the patented product and to the presence or absence of non-infringing substitutes; and

(c) any additional information which assists in the determination of whether lost profits may be appropriate and the amount thereof, [redacted] which again are relevant at a minimum to the demand for the patented product and the absence of non-infringing alternatives.

Shionogi expects—and Lupin has not denied—that Lupin will argue at trial that lost profits should not apply in this case. Indeed, Lupin's declarant, Ivan T. Hofman, has argued that Shionogi cannot prove that it would have made Lupin's sales (and therefore is not entitled to lost profits) because: [redacted].[1] Ex. E (April 23, 2012 Declaration of Ivan T. Hofmann) at ¶¶ 7-19. Accordingly, Shionogi is entitled to Lupin's

[1] Shionogi has suffered price erosion, at least because it and its partner, Watson, were forced to launch a lower-cost authorized generic product to compete with Lupin's generic copy of FORTAMET®.

documents that would either support, refute, or tend to refute these or other arguments that Lupin may make. Yet, Lupin seeks to deprive Shionogi of evidence within Lupin's possession that is directly relevant to Lupin's own arguments. Such documents include at least:

(a) Lupin's marketing plans and market analyses for its generic version of FORTAMET®;

(b) Lupin's communications with customers including its agreements with those customers;

(c) Documents concerning the distribution channels for Lupin's product and for FORTAMET®, including the participants in those distribution channels, the rebates and discounts in those channels, and any other documents tending to support or refute Lupin's distribution channel argument;

(d) Documents concerning the pricing of FORTAMET®, Lupin's generic product, and the authorized generic version of FORTAMET® currently being sold by co-Plaintiff Watson, including analyses of the impact of Lupin's sales on the sales of FORTAMET® and the authorized-generic, including on price and documents showing that Lupin anticipated the possible launch of an authorized generic; and

(e) Any other documents tending to support or refute Lupin's arguments.

(b) Reasonable Royalty

Shionogi also expects—and again, Lupin has not denied—that Lupin will argue that the appropriate measure of damages in this case is a reasonable royalty; and alternatively, that Lupin's sales may have "expanded" the market for FORTAMET®, such that any sales above and beyond what Shionogi would have sold but for the infringing conduct, Shionogi is entitled only to a reasonable royalty.

A reasonable royalty is generally determined by considering a hypothetical negotiation between Shionogi (the patentee) and Lupin (the alleged infringer) immediately prior to the first infringing act. This negotiation assumes, amongst other things, that the patent is valid and enforceable and that all relevant business facts are known by both parties. There are a large number of factors, typically referred to as the *Georgia-Pacific* factors, that fall generally into four categories: (1) licensing considerations generally; (2) benefits of the technology; (3) contributions to profits; and (4) respective bargaining positions. *See, e.g.*, *Micro Chemical, Inc. v. Lextron, Inc*., 317 F. 3d 1387, 1393 (Fed. Cir. 2003) (applying the *Georgia-Pacific* factors). The discovery sought by Shionogi falls squarely within these standard, well-established categories. Documents in Lupin's possession, relevant to establishing a reasonable royalty include:

(a) Licensing considerations: Lupin's documents concerning the licensing and the distribution of its product, discussions Lupin had with other companies regarding the potential sale of its ANDA;

(b) Benefits of the technology: Lupin's documents concerning the use of the patented invention in Lupin's products, potential non-infringing alternatives to Lupin's products, marketing and sales documents and marketing projections;

(c) Contributions to profits: Lupin's documents concerning the distribution, net and gross sales, discounts and rebates, returns, cost of goods, the relevant market and market share, monetary investment by Lupin in the product, marketing and sales plans, market projections, financial projections, including information relating to price erosion and elasticity, the impact of the products on Lupin's overall business; and;

(d) Respective bargaining positions: Lupin's documents concerning the importance, or lack thereof, of the product to its overall business, including documents concerning its profit margin, marketing and sales plans, and financial projections.

(c) Secondary Considerations of Non-Obviousness

The requested discovery is also relevant to secondary considerations of non-obviousness. Objective evidence of non-obviousness includes evidence that the patented invention has enjoyed commercial success, others recognized the value of the invention, and the invention satisfied a long-felt need. *Graham*, 383 U.S. at 17; *Proctor & Gamble Co., v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009). Recognition of the commercial success and value of the patented product can be shown by [redacted] and also by marketing and sales materials. Evidence concerning the profitability of the infringing product is also relevant to these considerations. *3Com Corp. v. D-Link Sys., Inc.*, No. 03-2177-VRW, 2007 WL 949596, at *4 (N.D. Cal. Mar. 27, 2007) (sales and other financial information relevant to secondary considerations of non-obviousness). Lupin should not be permitted to simultaneously argue that the patents in suit are invalid as obvious and block discovery relevant to refute that challenge.

(d) The Permanent Injunction Analysis

One of the remedies Shionogi seeks in this case is a permanent injunction against further infringement by Lupin. Shionogi expects that Lupin will argue, as it did during the preliminary injunction proceeding, that Lupin would be harmed if the Court permanently enjoins it. More specifically, during the preliminary injunction proceedings, Lupin argued that [redacted] *See* D.I. 239 (Declaration of Robert Hoffman) at ¶ 22. Lupin also argued that if enjoined [redacted] *Id.* at ¶ 23. Accordingly, discovery regarding Lupin's contractual relationship with its customers and communications with those customers, its ability to gain and maintain

market share, the profitability of its ANDA product, and its market projections, forecasts, and strategy is also relevant to the permanent injunction analysis.

(e) Damages to Lupin up to the Bond Amount

During the preliminary injunction proceedings, the Court set a $15 million bond. If Lupin ultimately succeeds in proving the patents in suit invalid and/or not infringed, then it must prove its damages up to the amount of the bond. Lupin will have to offer "sufficient and particularized evidence" that the injunction proximately caused its alleged damages, as well as the quantum of those damages. *Latuszewski v. VALIC Fin. Advisors, Inc.*, 393 F. App'x 962, 967 (3d Cir. 2010). Accordingly, the same discovery sought by Shionogi here is also relevant to Lupin's potential damages and causation.

3. Individual Document Requests

With the legal background set forth above, we now turn to a detailed discussion of each outstanding document request to Lupin. As will be seen, each request has been narrowed significantly by Shionogi, and each remaining narrowed request falls squarely within one or more categories of relevant damages discovery, well-established by extensive legal precedent. It is only Lupin's ongoing, blanket refusal to produce such traditional damages discovery that is extraordinary.

> **REQUEST FOR PRODUCTION 33.** All documents and things concerning the At-Risk Launch, including without limitation all documents concerning the manufacture, importation, sale, offer for sale, or shipment by Lupin (or any party acting on Lupin's behalf) of Lupin's ANDA Metformin Products, communications or agreements with third parties or customers regarding the At-Risk Launch, documents that identify the benefits to Lupin of the At-Risk Launch, and documents that identify the persons involved in the At-Risk Launch.

Because Shionogi and Lupin agreed that much of the information sought by this request is covered by other, more specific requests, the dispute concerning this request has been narrowed to ***communications concerning Lupin's actual sales, particularly those since September 2011***.[2] Although Lupin has agreed to produce responsive internal communications (even though it has yet to do so), it continues to refuse to produce any external communications, for example, communications with its customers, distributors, or payors.

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[2] In Shionogi's Second Set of Requests for Production of Documents and Things to Lupin (Ex. B), which contain the Damages Requests, Shionogi defined the At-Risk Launch as "Lupin's importation and sale of Lupin's ANDA Metformin Products on or around September 30, 2011, and any subsequent importation and sale of Lupin's ANDA Metformin Products." At the March 24 meet-and-confer, Lupin agreed that this definition encompassed Lupin's re-launch of product on or around April 18, 2012, and any subsequent importations and sales.

As an initial matter, such communications are necessary to verify and provide additional context for the customer-specific gross and net sales figures in Lupin's proposed spreadsheet, and to provide the identities of relevant witnesses necessary for Shionogi's damages claim.[3] At the very least, such discovery is reasonably calculated to lead to the discovery of potentially admissible evidence. Such discovery is also clearly relevant to the *Panduit* factors, particularly to showing demand for the patented product and to the absence of acceptable non-infringing alternatives. *Rite-Hite*, 56 F.3d at 1545. Such discovery is also relevant to Lupin's arguments (as set forth above) that lost profits should not apply because it may illuminate the factors driving Lupin's sales; Lupin's arguments concerning generic substitution laws; its arguments regarding the alleged differences in distribution channels; and its assertion regarding lack of price erosion.

Moreover, such external communications—such as Lupin's negotiations of prices, discounts, rebates, and formulary position—are relevant and necessary to the reasonable royalty calculation, as they may inform, at the very least: (1) the rates Lupin pays for patents similar to Shionogi's; (2) to whom Lupin's ANDA product is sold and on what terms; (3) sales of Lupin's other products that may be generated or enhanced by sales of its ANDA product; (4) the advantages of FORTAMET® over the competition; and (5) the portion of Lupin's profit that can be attributed to Shionogi's invention; and the hypothetical negotiation. *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

This Court has already rejected Lupin's unsubstantiated blanket claims of sensitivity with respect to these documents, and, by offering the proposed spreadsheet with customer-specific information, Lupin has now conceded that such information is relevant and not too sensitive to produce (at least to Shionogi). Further, Lupin has already produced at least one external communication that led to the discovery of potentially relevant information, *see* Ex. C [redacted], and Lupin has requested precisely this same kind of information from Shionogi, *see* Ex. D (Lupin's Third Set of Requests for the Production of Documents and Things).

As such, in addition to Lupin's internal communications, Shionogi requests that the Court order Lupin to produce within ten days all of its external communications regarding the importation and sale of its ANDA product.

> **REQUEST FOR PRODUCTION 35.** All document and things concerning the distribution in the United States of Lupin's ANDA Metformin Products.

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[3] Lupin has recently used communications and other damages-related documents produced by Shionogi to identify former Shionogi sales employee Joel Kelly, whom Lupin now plans to subpoena to testify to damages issues. Lupin should not be permitted to deny Shionogi the same opportunity.

> **REQUEST FOR PRODUCTION 36.** All documents and things concerning the sale or offer for sale by any person (including third parties) of Lupin's ANDA Metformin Products.

Shionogi has narrowed these requests to seek only documents ***sufficient to: (1) identify all entities in the chain of distribution from Lupin to the end user of its ANDA product, and (2) show any further discounts or rebates offered by or to those entities.*** As Shionogi explained to Lupin, the ultimate price paid by end users is relevant at a minimum to Shionogi's long term lost profits and price erosion. Lupin responded by repeating its arguments from the May 11 hearing that such information is highly sensitive and that Shionogi cannot claim price erosion because it has not—to date—in fact lowered its prices. As such, Lupin categorically refused to produce this information. In other words, Lupin is attempting to block discovery on the basis that it should prevail on the merits. This is improper.

As to lost profits, Lupin's own expert has conceded that the chain of distribution for pharmaceutical products is exceedingly complex, [redacted] *See* Ex. E (Hofmann Decl.) at ¶¶ 24-25 (emphasis added). And as explained by Shionogi's expert, Christopher Gerardi, this is precisely why Lupin must produce documents sufficient to show its particular distribution network, such that Shionogi can appropriately understand the ultimate profitability of Lupin's product. This informs whether Shionogi would have made a particular sale to a particular Lupin customer. *See* Ex. F (May 1, 2012 Declaration of Christopher Gerardi) at ¶ 3(g) [redacted]; *see also* Ex. G (sample Shionogi drug distribution chart).

Moreover, as to price erosion, Lupin's contention that Shionogi has not lowered prices is incorrect. The introduction of the lower-priced authorized generic version of FORTAMET®, by Shionogi's partner, Watson, is a textbook example of price erosion. Because FORTAMET® cannot effectively compete with Lupin's lower-priced generic version of that product, Plaintiffs were forced to introduce a lower-priced generic product of their own. Shionogi's profits on the sales of this lower-priced authorized generic product are lower than they would be if the same sale were made of FORTAMET®, a direct result of Lupin's infringement.

Accordingly, Shionogi requests that the Court order Lupin to produce within ten days documents sufficient to identify each entity throughout the chain of distribution of its ANDA product and to sufficient to show further discounts offered by them to end users.

> **REQUEST FOR PRODUCTION 37.** All documents and things concerning any agreement by Lupin with any third party relating to Lupin's ANDA Metformin Products, including without limitation all documents relating to the negotiation of any such agreement.

> **REQUEST FOR PRODUCTION 45.** All documents and things concerning any agreement by Lupin with a third party regarding the importation, sale, or offer for sale of Lupin's ANDA Metformin Products, including without limitation any licensing, supply, distribution, warehousing, shipping, insurance, or re-insurance agreement.

At the May 24 meet-and-confer, Shionogi narrowed these requests to seek only [redacted] Once again, Lupin asserted without justification or specificity that the documents were "highly sensitive" and categorically refused to produce any.

These documents—which are discrete, of limited volume, and easily producible—are highly relevant and necessary to Shionogi's damages claim. As noted above, and as Lupin concedes, the distribution chain for pharmaceutical products varies widely by company, and can involve individualized terms, discounts, rebates, and considerations based on a number of factors. And because lost profits and reasonable royalty are typically calculated on a customer-by-customer basis, Lupin's agreements with individual customers are important. Moreover, Lupin itself requested, and Shionogi has already produced, dozens of such agreements (along with the information contained therein in spreadsheet form) *to Lupin*. *See, e.g.*, Ex. H [redacted]

During the meet-and-confer, Shionogi likewise reiterated that [redacted] is also relevant and discoverable, and is responsive to these requests. Lupin and Mylan disagreed. *But see* Ex. A at 68:18-20 [redacted]. Although Shionogi maintained and continues to maintain that [redacted] is responsive to the Damages Requests,[4] for the avoidance of any doubt, Shionogi served both Lupin and Mylan with targeted requests [redacted] on May 30, 2012.

On June 27, 2012, Lupin informed Shionogi that it anticipated producing [redacted] on July 3, 2012. *See* Ex. I (email from Lupin to Shionogi, dated June 27, 2012). Lupin also asserted that Shionogi's request for documents related to [redacted] *Id.*

Although Shionogi accepts this offer as better than nothing, Lupin should also be ordered to produce within ten days communications, non-privileged drafts, and other documents related to [redacted] is relevant to

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[4] It is clear that Document Request No. 45—for "[a]ll documents regarding any agreement by Lupin with a third party . . . regarding the sale . . . of Lupin's ANDA Metformin Products"—captures [redacted].

both the lost profits analysis (demand for the patented product), as well as to the reasonable royalty analysis [redacted] the benefits of the invention over the prior art), and will help put [redacted] in context. *See*, *e.g.*, *Bose Corp. v. JBL, Inc.*, 112 F. Supp. 2d 138, 165 (D. Mass. 2000). At the very least, such discovery is reasonably calculated to lead to the discovery of potentially admissible evidence.

Accordingly, Shionogi requests that the Court order Lupin to produce, within ten days, agreements or contracts with customers and other entities in the chain of distribution and all documents associated with [redacted].

> **REQUEST FOR PRODUCTION 40.** All documents and things concerning bills of lading, invoices, or shipping records related to the At-Risk Launch, including without limitation documents concerning the importation, sale, offer for sale, or shipment of Lupin's ANDA Metformin Products.
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> **REQUEST FOR PRODUCTION 41.** All documents and things concerning the sale of Lupin's ANDA Metformin Products, including without limitation all documents that: 1) identify each party to which Lupin's ANDA Metformin Products have been shipped or sold; 2) concern the unit quantity of 500 mg and 1000 mg tablets of Lupin's ANDA Metformin Products that were shipped or sold to each party; 3) concern the price at which each 500 mg or 1000 mg tablet was sold or shipped to each party; 4) concern the profits received for each such sale; 5) concern the date that Lupin's ANDA Metformin Products were shipped or sold to each party; and 6) concern the reason why each party was selected for shipment or sale.
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> **REQUEST FOR PRODUCTION 42.** All documents and things concerning the pricing of Lupin's ANDA Metformin Products, including without limitation all documents concerning any discounts or rebates for Lupin's ANDA Metformin Products, whether any sale was made pursuant to a mandatory substitution law, the formulary status given to Lupin's ANDA Metformin Products on or after the sale, and any analysis performed prior to and in support of establishing the price of Lupin's ANDA Metformin Products.

At the May 24 meet-and-confer, Shionogi narrowed these three requests to seek only ***information regarding the shipment, sales, and pricing of Lupin's ANDA product separated by customer***. Lupin's proposed spreadsheet presumably provides some of this information. However, the spreadsheet as proposed by Lupin (though not yet produced) would omit key information and, in any event, does not substitute for the underlying documents themselves, which undoubtedly contain other discoverable information.

Shionogi is entitled to the underlying information with which to test the data contained in Lupin's spreadsheet, such as the components that go into determining gross versus net sales. These documents include customer agreements, invoices, bills of lading, rebate offers, discount offers, and return verifications. These documents also contain relevant details (such as

unique contract terms and rebate offers) that a spreadsheet cannot provide. And Shionogi is entitled to documents identifying relevant Lupin employees in order to prepare for depositions and trial. Shionogi has produced similar documents to Lupin and, given Shionogi's clarification and narrowing of these requests, Lupin has no remaining justification for refusing to produce these documents.

Shionogi also requests that Lupin be ordered to include in the spreadsheet the following, readily available information: (1) the date of each sale or shipment to each customer; (2) each discount provided to each customer; (3) each rebate provided to each customer; and (4) each return by each customer, if any. These facts are relevant to understanding whether Shionogi would have made the sale at a particular time (demand for the patented product) as well as profitability, which may vary depending on the date of sale—all of which goes directly to Shionogi's burden to prove that "but for" Lupin's infringement, Shionogi would have made those sales. The number of returns is relevant because if a product is returned it reduces the effective number of units sold, which in turn could increase Shionogi's profitability if Shionogi would have sold the same number of units but without any returns.

Accordingly, Shionogi requests that the Court order Lupin to produce, within ten days, these documents.

> **REQUEST FOR PRODUCTION 79.** All documents and things concerning financial information concerning Lupin's ANDA Metformin Products and Lupin's At-Risk Launch, including without limitation: 1) business plans; 2) actual or forecasted projected gross and net sales; 3) actual or forecasted projected costs and expenses associated with Lupin's ANDA Metformin Products; 4) administrative or overhead expenses, costs of raw materials or API (active pharmaceutical ingredient), production costs, and royalties paid; 5) method(s) used by Lupin to determine net profit margins and an explanation of all measures of profit used in connection with Lupin's ANDA Metformin Products, including gross profit, operating profit, and/or Contribution A; 6) sharing of revenue or profits earned on Lupin's ANDA Metformin Products between the Lupin entities which are parties to this case and any other entities including any agreement concerning or reflecting such profit-sharing; and 7) the reasons for any difference between Lupin's pre-At-Risk Launch projected, forecasted, planned, or budgeted revenue and profit from sales of Lupin's ANDA Metformin Products and post-At-Risk Launch actual revenue and profit.

At the May 24 meet-and-confer, Shionogi narrowed this request significantly to seek only ***information on the profitability of Lupin's ANDA product and Lupin as a whole, in particular the cost of goods sold***. Lupin objected and continues to object on sensitivity grounds, abstractly claiming that profitability information could allow a competitor to understand and therefore undercut its business. This argument is overbroad and without merit, especially in light of the Court's robust, two-tiered protective order. Further, Shionogi has explained to Lupin that profitability information does not involve Lupin's customers, and therefore presents even less of

a sensitivity concern than other requested information which Lupin has agreed to produce and which the Court has ordered produced.

Shionogi requires Lupin's profitability information at least because it informs how much Lupin would be willing to offer as a reasonable royalty during the hypothetical negotiation. *See Radio Steel & Mfg. Co. v. MTD Products, Inc.*, 788 F.2d 1554, 1557 (Fed. Cir. 1986) (approving district court's royalty analysis because infringer "expected to make a net profit of about six percent on its sale of infringing wheelbarrows."). Further, if Lupin's infringement resulted in savings to the company as a whole, its profits margins would be higher and Shionogi would have negotiated accordingly. *See Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1080-81 (Fed. Cir. 1983) ("Reliance upon estimated cost savings from use of the infringing product is a well settled method of determining a reasonable royalty.").

Accordingly, Shionogi requests that the Court order Lupin to produce, within ten days, documents sufficient to show the profitability of Lupin's ANDA product and Lupin as a whole, including but not limited to the cost of goods sold.

4. Shionogi's Expedited Interrogatories No. 1 and 2

> **INTERROGATORY NO. 1.** Identify each sale and/or shipment of Lupin's generic metformin product, and for each sale and/or shipment, identify (a) the customer; (b) the unit quantity of 500 mg and 1000 mg tablets; (c) the price per unit quantity; (d) the date of shipment and receipt by the customer; (e) any rebates and/or discounts given; and (f) any contracts or agreements with said customer relating to Lupin's generic metformin product.
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> **INTERROGATORY NO. 2.** Identify and produce all documents reviewed or consulted in responding to Interrogatory No. 1.

For the reasons listed above, Shionogi requests that the Court order Lupin to, within ten days, respond to these interrogatories, given that the information is both relevant and necessary. Further, because these interrogatories cover the same material that the Court has already found discoverable and not sensitive, and is information that Lupin has already agreed to produce via its proposed spreadsheet, Lupin has no remaining justification for not responding to these interrogatories.

B. Lupin Has Not Produced Promised Documents

As noted above, despite this Court's orders and Lupin's repeated assertions that it will produce certain documents, Lupin has to date not done so and moreover refuses to provide a date or even an estimated date for production.[5] The documents are:

[5] Although Shionogi has repeatedly asked Lupin why Lupin cannot provide even an estimated date for production, Lupin has provided no answer as to most documents. As

1. internal Lupin communications regarding the importation and sale of its ANDA product (Document Request No. 33);

2. documents regarding the importation into the United States of Lupin's ANDA product (Document Request No. 34);

3. batch records for the manufacture of Lupin's ANDA product (Document Request No. 38);

4. additional forecasts and analyses regarding Lupin's sales and pricing (Document Request No. 42), market share (Document Request No. 43); marketing and distribution (Document Request No. 44), and forecasting, budgeting, and financial or strategic planning (Document Request No. 53);[6] and

5. additional documents related to [redacted] including documents within the possession of [redacted] (Document Request Nos. 57-63).

Since the May 11 hearing, Lupin has produced a single page in discovery: a heavily-redacted table purporting to contain the net sales and total units sold of Lupin's ANDA product through April 2012. *See* Ex. J [redacted]). In contrast, Shionogi substantially completed its production on May 25, 2012.[7] Shionogi's production contains many of the same types of information Lupin has claimed is "too sensitive," including third-party agreements, sales and rebate information by customer, sales information for other drugs, and profitability information. In accordance with the Court's prior order to Lupin that it "promptly produce the

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to forecast documents, Lupin has replied that the documents are in "more than one location" at the company. Nevertheless, Lupin has found time to serve dozens of additional document requests, multiple letters alleging miniscule document production deficiencies (many of which are now being raised for the first time even though Shionogi produced many of those documents in March 2011), and requests for supplemental interrogatory responses.

6 Lupin has been promising these forecasts since it submitted its briefing prior to the May 11 hearing. *See, e.g.*, Ex. A at 53:7-11.

7 On June 4, 2012, Lupin sent Shionogi a letter outlining alleged deficiencies in Shionogi's production. Ex. K (letter from Lupin to Shionogi, dated June 4, 2012). Although most of these deficiencies concern Shionogi productions from as early as March 2011, and involve searching document warehouses and email servers of employees who have since left Shionogi, Shionogi is investigating the alleged deficiencies and intends to produce a written response as well as supplementary documents, if any exist, as soon as possible. Shionogi explained this to Lupin during a third meet-and-confer on June 13, 2012, and by letter on June 26, 2012. *See* Ex. L (letter from Shionogi to Lupin, dated June 26, 2012).

documents it agreed to produce," D.I. 462 (May 31, 2012 Letter Order), Shionogi requests that the Court order Lupin to produce these documents within five days.

C. Other Discovery Issues

1. Samples of Lupin's ANDA Product

On May 23, 2012, Shionogi sent Lupin a letter requesting 150 representative tablet samples of Lupin's 500 mg and 1000 mg ANDA products taken from at least 15 different manufacturing lots, *see* Ex. M (letter from Shionogi to Lupin, dated May 23, 2012), given that the samples Lupin had previously produced in response to Document Request No. 29 have expired. At the June 5 meet-and-confer, Lupin asserted that it would treat the letter request as a formal discovery request and respond within the timeframe allowed by the Federal Rules. On June 25, 2012, Lupin responded by offering 150 representative samples of each of its 500 mg and 1000 mg ANDA products, but from only *one* manufacturing batch. *See* Ex. N (Lupin Defendants' Responses to Shionogi's May 23, 2012 Request for Representative Samples of Lupin's ANDA Product). Once again, Lupin claimed without justification that Shionogi did not need the number and variety of samples requested.

Lupin's ANDA product is not only relevant to, it is the center of this litigation—as evidenced by Lupin's previous production.[8] To the extent any detailed justification is necessary, Shionogi requires multiple lots to determine whether Lupin's product exhibits variance between batches. Variance between batches can cause variance in the dissolution profile of the product, and some of the patent claims in dispute concern dissolution profile. *See* Pharmacopoeia § 1092 - The Dissolution Procedure: Development and Validation ("The acceptance criteria should be representative of multiple batches with the same nominal composition and manufacturing process, typically including key batches used in pivotal studies, and representative of performance in stability studies. . . . It is also possible for the procedure to show differences between batches when no significant difference is observed in vivo."); *see also* 21 C.F.R. § 211.110(a) ("To assure batch uniformity and integrity of drug products, written procedures shall be established and . . . conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.").

Shionogi therefore requests that the Court order production of all the samples requested in Shionogi's May 23 letter within ten days.

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[8] And once again, Lupin has erected obstacles to production of material that Lupin itself seeks from Shionogi. *See* Ex. N (Lupin's Fifth Set of Requests for Production) (seeking samples of FORTAMET® without providing any of the justifications it demands of Shionogi).

2. Redactions in Lupin's Production

Shionogi has identified at least 250 documents in Lupin's production that contain unexplained redactions. To the extent that any information in Lupin's production has been redacted based on Lupin's claims of sensitivity and confidentiality, these claims have been rejected by this Court and have been undermined by Lupin's offer to produce information it previously sought to withhold on these grounds. As such, any redactions based on Lupin's rejected sensitivity claims should now be removed and the documents reproduced without them within ten days. *See, e.g.*, Ex. C [redacted]

D. Request for Sanctions

Pursuant to Rule 37(b)(2)(C), Shionogi seeks reasonable expenses, including attorneys' fees, as a sanction for the additional meet-and-confers and the additional time and resources required to brief this letter on account of Lupin's continued assertion of sensitivity claims rejected by this Court. Shionogi also seeks reasonable expenses, including attorneys' fees, for Lupin's failure to produce documents in violation of the Court's May 31, 2012 letter order, which has prejudiced Shionogi's ability to prepare for depositions and trial.

II. DISCOVERY DISPUTES WITH MYLAN

A. Mylan 30-Month Stay Expiration

By virtue of the Hatch-Waxman statute, the filing of this lawsuit against Mylan resulted in an automatic 30-month stay of FDA approval for Mylan's ANDA. Both Shionogi and Mylan agree that [redacted] *See* Ex. O (email from Shionogi to Mylan, dated June 11, 2012).

Since March 27, 2012, Shionogi has repeatedly asked Mylan whether it would agree to provide 60 days' notice prior to launching the commercial sale of its ANDA product in order to allow adequate time for briefing regarding a preliminary injunction. *See* Ex. P (letter from Shionogi to Mylan, March 27, 2012). To date, Mylan has refused to respond. Prior to the April 5 discovery hearing before this Court, Mylan represented that it would consider the request. *See* D.I. 389 (letter from Shionogi to Magistrate Judge Schneider, dated April 2, 2012) at 14. Having waited over a month for a response, on May 24, 2012, Shionogi again requested that Mylan agree to provide notice of a commercial launch. *See* Ex. Q (email from Shionogi to Mylan, May 31, 2012). Again receiving no response from Mylan, Shionogi repeated its request at least two more times. *See* Ex. R (email thread between Shionogi and Mylan, dated May 23 - June 27, 2012). Despite Shionogi's multiple requests for an answer, Mylan continues to avoid providing a substantive response.

Mylan has known since October 27, 2011 that the FDA gave tentative approval of Mylan's ANDA, noting that final approval could not be granted until the expiration of the 30-month statutory period. *See* Ex. S (MYLF00000842-843). Yet, Mylan waited almost seven months after receiving tentative approval and almost two months after receiving Shionogi's

request for notice of launch, before it actually produced the FDA's letter to Shionogi. Ex. T (letter from Mylan to Shionogi, dated May 10, 2012). At the time that the stay expires, Mylan will have had almost [redacted] of notice that the FDA is prepared to grant final approval. During a meet and confer on June 29, 2012, counsel for Mylan represented that they were unable to provide a response on whether Mylan would be willing to give Shionogi notice prior to launch, but would inform Shionogi once they had final approval from the FDA. Shionogi has no way of knowing whether Mylan is intending to launch its product upon receiving final approval from the FDA, and it is unreasonable for Mylan to continue to avoid responding to Shionogi's requests regarding whether it is willing to provide notice of such a launch.

As the stay is set to expire [redacted] and Mylan has not yet agreed to provide adequate notice for Shionogi to seek and obtain a preliminary injunction, Shionogi respectfully requests that the Court set a briefing schedule for such a motion, unless Mylan agrees to provide sufficient pre-launch notice to enable timely briefing and decision by the Court.

B. Samples of Mylan's ANDA Product

On May 23, 2012, Shionogi also requested that Mylan produce 150 representative tablet samples of its 500 mg and 1000 mg ANDA products taken from at least 15 different manufacturing lots, *see* Ex. U (letter from Shionogi to Mylan, dated May 23, 2012), as the samples Mylan had previously produced in response to Document Request No. 29 have expired.

Document Request No. 29 states:

> 29. Samples of Mylan's ANDA products as well as the materials that make up Mylan's ANDA products, and documents sufficient to identify the process by which they were made, including but not limited to batch records, certificates of analysis, and documents sufficient to show whether the samples are representative.

Mylan responded on June 5 that it was "not aware of the existence of any unexpired samples." *See* Ex. R (email from Mylan to Shionogi, dated June 5, 2012). Due to the ambiguity of Mylan's response, Shionogi sought further clarification to verify that, other than the validation batches originally manufactured for the submission of Mylan's ANDA, Mylan had not made nor was currently making any batches of the extended release metformin tablets described in its ANDA (as such products would be covered under Document Request No. 29). *Id.* In this same correspondence, Shionogi repeated its request for Mylan to provide notice prior to its commercial launch. *Id.* Mylan did not provide any response until the meet and confer held on June 29, 2012. During this call, Mylan's counsel represented that Mylan had no unexpired product, that they have not manufactured any product since the lots that were used to file the ANDA, and that they were unaware of any current production.

Given Mylan's evasive conduct with respect to issues related to its launch plans, Shionogi respectfully requests that the Court order Mylan to make clear whether it is in the

possession of any unexpired products that are within the scope of Document Request No. 29, and if so, to promptly produce the requested samples to Shionogi.

C. Document Request Nos. 67-68

On May 25, 2012, Shionogi served a Third Set of Requests for the Production of Documents and Things to Mylan Defendants (Nos. 67-68). *See* Ex. V. These two requests seek documents regarding [redacted].

REQUEST FOR PRODUCTION 67. [redacted]

REQUEST FOR PRODUCTION 68. [redacted]

Mylan objects to producing any documents in response to Request Nos. 67-68 as not reasonably calculated to lead to the discovery of admissible evidence, stating that the documents are irrelevant as only related to issues of willfulness or damages. As already explained above, this discovery is relevant to secondary considerations of non-obviousness, at a minimum, and for this reason, Mylan should be required to produce responsive documents.

Objective evidence of non-obviousness includes evidence that the patented invention has enjoyed commercial success, others recognized the value of the invention, and the invention satisfied a long-felt need. *Graham*, 383 U.S. at 17; *Proctor & Gamble Co., v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009). That others recognized the commercial success and value of the patented product can be shown by the fact that [redacted] through Lupin's sales of infringing product, and also by marketing and sales materials. Evidence concerning the profitability of the infringing product is also relevant to these considerations. *3Com Corp. v. D-Link Sys., Inc.*, No. 03-2177-VRW, 2007 WL 949596, at *4 (N.D. Cal. Mar. 27, 2007) (sales and other financial information relevant to secondary considerations of non-obviousness). Mylan should not be permitted to simultaneously argue that the patents in suit are invalid as obvious and block discovery relevant to refute that challenge.

Shionogi therefore respectfully requests that the Court order Mylan to produce any documents in its possession that are responsive to Document Request Nos. 67-68.

Respectfully submitted,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

KJL/jy
Enclosures

cc: All Counsel of Record
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